

REMARKS

Claims 1-5 and 7-23 are pending in the application and are presented for the Examiner's review and consideration. In this Response, claims 1 and 15 have been amended; and claim 6 has been cancelled. Applicants believe that the claim amendments, cancellations, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that they do not limit the range of any permissible equivalents.

35 U.S.C. § 103(a)

Claims 1-3, 6-9, 12-18, and 20-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,407,420 to Bastyr et al. ("Bastyr") in view of U.S. Patent No. 5,417,643 to Taylor ("Taylor"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are patentable over Bastyr in view of Taylor.

As discussed in the prior Responses, Bastyr fails to disclose a shoulder orthosis device as set forth in the instant claims. In this interest of brevity, Applicants do not repeat this discussion here. Rather, the focus is on the assertion that Bastyr includes a drive member, identified as items 54 and 56 in the Office Action.

Bastyr discloses a rigid metal upper arm linkage 54 is attached to the upper arm cuff 28 in a freely rotatable manner by means of a rotatable mounting assembly 56. (Col. 5, lns. 20-22). The linkage 54 comprises a female bar 60 having a male bar 62 extending therefrom to provide telescopic adjustment of the length of the linkage 54, thereby enabling fitting of the brace 10 to different arm lengths. (Col. 5, lns. 24-29).

The mounting assembly 56 comprises a mounting member 114, rivets 116a, 116b, and a stiffener 118. (Col. 6, lns. 51-53). The rivet 116a extends through the upper arm linkage 54,

mounting member 114, stiffener 118, and upper arm cuff 28, thereby serving as an axis of rotation to enable free rotation of the cuff 28 about the rivet 116a relative to the linkage 54. (Col. 6, lns. 53-58). The rivet 116b fixes the stiffener 118 to the cuff 28. (Col. 6, lns. 58-59).

The length of the upper arm assembly linkage 54 can be adjusted to fit the upper arm of the patient irrespective of the position of the rotation adjustment nut 188 without altering its position. (Col. 10, lns. 43-46). Length adjustment is provided by turning the length adjustment nut 190 in one direction to threadably draw the male bar 62 from the distal opening 218 of the female bar 60 and lengthen the linkage 54. . (Col. 10, lns. 46-50).

As such, item no. 54 is a linkage having a female bar and a male bar extending therefrom. The linkage is attached to upper arm cuff with mounting assembly 56, where the mounting assembly includes rivets and a stiffener. Referring to Figure 1 in Bastyr, the linkage (54) and the mounting assembly (56) are positioned on the underside of the arm. The length of the linkage is adjustable by the rotation of an adjustment nut, which extends or retracts the male bar from the female bar.

However, Bastyr fails to disclose that the linkage and mounting assembly are connected to the lower arm section and can be manually operable by the patient to rotate the lower arm portion about the central longitudinal axis of the humerus bone. Furthermore Bastyr fails to disclose that the linkage and mounting assembly includes an opening configured, dimensioned, and arranged to accommodate a section of the patient's arm therein.

The secondary reference, Taylor, fails to overcome the deficiencies in Bastyr. For example, Taylor fails to disclose a drive member including an opening configured, dimensioned, and arranged to accommodate a section of the patient's arm therein.

Claim 1 recites, *in part*, a shoulder orthosis device for effecting rotational movement of a lower arm portion of a patient's arm about a central longitudinal axis of a humerus bone of an upper arm portion of the patient's arm. The shoulder orthosis including a drive member operably connected to the lower arm section and manually operable by the patient to rotate the lower arm portion about the central longitudinal axis of the humerus bone such that the lower arm portion is

maintained substantially orthogonal to the upper arm portion. The drive member has an opening configured, dimensioned, and arranged to accommodate a section of the patient's arm therein.

Claim 15 includes similar elements.

In light of the foregoing, independent claims 1 and 15 are respectfully submitted to be patentable over Bastyr in view of Taylor. As claims 2, 3, 7-9 and 12-14 depend from claim 1 and claims 16-18 and 20-22 depend from claim 15, and necessarily include all the elements of their base claims, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

Claims 4, 5, 10, 11, and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bastyr in view of Taylor in further view of U.S. Patent No. 5,538,499 to Schween et al. ("Schween"). The inclusion of Schween fails to overcome the deficiencies in Bastyr and Taylor. As claims 4, 5, 10 and 11 depend from claim 1 and claim 19 depends from claim 15, and necessarily include all the elements of their base claims, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

In light of the foregoing, claims 4, 5, 10, 11, and 19 are respectfully submitted to be patentable over Bastyr in view of Taylor in further view Schween.

#### Allowed Claim

Applicants acknowledge with appreciation the indication that claim 23 is allowed.

#### Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$60.00 under 37 C.F.R. 1.17(a)(1) for a one month extension of time is believed

Applicant: Bonutti et al.  
Application No.: 10/760,598  
Examiner: M. Brown

due and is being paid via Credit Card. Please charge any additional fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-006-3).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P.D. Bianco", with a stylized flourish at the end.

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771  
Paul D. Bianco  
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO  
21355 East Dixie Highway, Suite 115  
Miami, Florida 33120  
Tel: 305-830-2600; Fax: 305-830-2605  
e-mail: [pbianco@focusonip.com](mailto:pbianco@focusonip.com)